

# **EXHIBIT 2**

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September 12, 2007

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IN THE CIRCUIT COURT OF  
MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA, )  
Plaintiff, ) Case No.  
vs. ) CV-05-219  
ABBOTT LABORATORIES, INC., ) Judge Charles  
et al., ) Price  
Defendants. )

STATE OF WISCONSIN CIRCUIT COURT  
DANE COUNTY

STATE OF WISCONSIN, )  
Plaintiff, )  
vs. ) CASE NO.  
AMGEN INC., et al., ) 04-CV-1709  
Defendants. )

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1 identification.)

2 BY MR. TORBORG:

3 Q. For the record, what I've marked as  
4 Exhibit Abbott 298 is a Westlaw printout of  
5 certain portions of the proposed rule dated June  
6 5th 1991 for fee schedule for physician services.  
7 The actual proposed regulation is quite long. I  
8 printed out portions that I wanted to ask you  
9 some questions about.

10 A. Okay.

11 Q. And I believe you stated earlier that  
12 this was an effort, this particular fee schedule  
13 regulation, that you were involved in, correct?

14 A. Correct.

15 Q. If I could direct you to the second  
16 page of the document that I've handed you. It  
17 has page 24 at the top?

18 A. Yes. Mm-hmm.

19 Q. The section under drugs states "The  
20 program currently pays for drugs furnished in  
21 physician's offices that are not self-  
22 administered under the incident 2 provision set

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1 forth in section 1861(s) (2) of the act."

2 And then the next paragraph states "We  
3 considered the following options for paying for  
4 drugs under the fee schedule: Option 1,  
5 establish a fee schedule amount for each drug."  
6 And option 2 was "Bundle the payment for the drug  
7 into payment for the visit or consultation  
8 service."

9 3, "Make a separate payment for a drug  
10 and leave the pricing of the drug to each  
11 carrier." Option 4, "Make a separate payment for  
12 a drug but require a consistent method in pricing  
13 to be used by the carriers." Correct?

14 A. Yes.

15 Q. And then below I believe the comments  
16 state that option 1 was rejected at least for the  
17 time being because it was not practical; is that  
18 correct?

19 A. Right.

20 Q. And do you recall that?

21 A. Yes.

22 Q. And there's reference to considering

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1 the issue in the future?

2 A. Mm-hmm.

3 Q. Do you recall whether that was  
4 considered in the future?

5 A. I don't think so.

6 Q. Do you know why not?

7 A. The press of other business.

8 Q. Option 2, "Bundle the payment for the  
9 drug into the payment for the visit or  
10 consultation service," was that --

11 A. Well, actually, let me just amend what  
12 I just said. I think the other reason was we  
13 were going down a different path in drug  
14 reimbursement looking to do at a lower percentage  
15 off AWP. So we decided -- we sort of went down  
16 that path and didn't go down the other path of  
17 trying to compute individual prices for a whole  
18 fee schedule for all drugs that Medicare uses at  
19 all dosing levels. Just a laborious, labor-  
20 intensive effort.

21 Q. In the paragraph under option 4, that  
22 next paragraph that starts "We believe," the last

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1 sentence states "Also we are proposing that we  
2 will instruct all carriers to base payment for  
3 drugs on 85 percent of the national average  
4 wholesale price of the drug (as published in the  
5 Red Book in and similar price listings), but we  
6 welcome comments regarding the appropriate  
7 discount."

8 Do you recall receiving comments  
9 regarding the appropriate discount?

10 A. I don't. But I am guessing there were  
11 comments.

12 Q. Who was responsible for reviewing the  
13 public comments that came in to your office as  
14 recognition --

15 A. Oh. We had a --

16 Q. For drugs?

17 A. Well, it's for everything. There was a  
18 regulation staff and the regulation staff has a  
19 fairly systematic way of bringing comments in, as  
20 many as forty to ninety thousand comments on  
21 certain regulations. So they catalogue them.  
22 Log them in, date stamp them.

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1                   And they try to categorize them by  
2 category in the regulation because different  
3 regulations have different staff involvement. So  
4 you've got to group them so that the staff who  
5 has to look at them has a binder like that  
6 (indicating) of the comments they have to review.  
7 And that staff, the regulation staff, is the one  
8 that pulls all the comments together.

9                   I believe the staff was headed up by a  
10 woman named Sue Brown, B-r-o-w-n, at the time  
11 this regulation was done.

12                  Q. In the next paragraph about three-  
13 fourths of the way down there's a sentence that  
14 starts with "moreover." Do you see that?

15                  A. No.

16                  Q. I think it's the third, fourth full  
17 sentence under the Medicare policy paragraph.

18                  A. Fifth from the bottom?

19                  Q. Second-to-last sentence from the bottom  
20 in the paragraph. "Moreover." It states  
21 "Moreover, we are proposing for very high volume  
22 drugs the payment for the drug would be limited

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1 to the lower of the estimated acquisition cost of  
2 the drug as determined by us and specified in  
3 instructions to carriers or 85 percent of the  
4 national average wholesale price for the drug."

5 A. Right.

6 Q. What did you mean when you say  
7 "national average wholesale price for the drug"?

8 A. AWP.

9 Q. As reflected in Red Book or a similar -  
10 -

11 A. Yes, or some other resource.

12 Q. Why did you propose this estimated  
13 acquisition cost option for very high volume  
14 drugs?

15 A. Because we didn't think that Red Book  
16 even a 15 percent discount was an accurate  
17 acquisition cost. We wanted to do a survey,  
18 actually look at the acquisition cost.

19 Q. You believed that for some drugs the  
20 discount might be greater than 15 percent?

21 A. Yes. And we were -- as you can see, we  
22 were looking for the low hanging fruit. We were

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1 looking for the high volume drugs where Medicare  
2 was probably a dominant payor.

3 (Exhibit Abbott 299 was marked for  
4 identification.)

5 BY MR. TORBORG:

6 Q. For the record, what I've marked as  
7 Exhibit Abbott 299 is a document that was I  
8 believe collected in counsel's review of public  
9 comments maintained by HCFA for this proposed  
10 regulation. This particular one comes from the  
11 National Medical Care, Inc. organization.

12 A. Right.

13 Q. I have a number of questions for you on  
14 this document, but let me start off with a few to  
15 start off with. Are you familiar with National  
16 Medical Care?

17 A. Yes.

18 Q. And what kind of an organization are  
19 they?

20 A. They run for-profit dialysis centers.

21 Q. If you would go to the third page of  
22 the document, the last paragraph, NMC wrote "As a

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1 technical matter it should be noted that while in  
2 the discussion of the proposal it is clear that  
3 HCFA proposes to pay 85 percent of AWP of a drug"  
4 -- and this is in italics -- "as published in  
5 redbook" -- end italics -- "the actual proposed  
6 regulatory language is '85 percent of the  
7 national average wholesale price of the drug" --  
8 and then in italics -- "as determined by HCFA.'

9 "In the first case, AWP is a category  
10 of data of questionable relationship to reality  
11 contained in the particular published source. In  
12 the second, AWP is empirically determined by HCFA  
13 and might in fact be an accurate reflection of  
14 prices paid. But certainly HCFA does not propose  
15 to pay 85 percent of the actual average  
16 acquisition cost - a policy which would result in  
17 none of the affected drugs being provided. This  
18 inconsistency needs to be eliminated."

19 And if you look back at the document I  
20 just showed you, the proposed legislation, on the  
21 last page of that exhibit, page 137 at the top,  
22 in fact in the payment rule they did -- that is

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1 how you defined AWP in that proposed regulation,  
2 correct? I'm under 42 C.F.R. section 415.34,  
3 section B, payment rule.

4 A. Okay.

5 Q. It states "Except as specified in  
6 paragraph D of this section, payment for drugs  
7 furnished incident to a physician's service is  
8 limited to 85 percent of the national average  
9 wholesale price of the drug as determined by  
10 HCFA," correct?

11 A. (Nods head).

12 Q. And that was the language that NMC had  
13 pointed out to you as being --

14 A. Yes.

15 (Exhibit Abbott 300 was marked for  
16 identification.)

17 MR. DRAYCOTT: With this document we  
18 reach another milestone?

19 MR. TORBORG: Yes. Exhibit Abbott 300.

20 BY MR. TORBORG:

21 Q. Ms. Buto, what we've marked as Exhibit  
22 Abbott 300 is another comment that was obtained

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1 by counsel in reviewing the public comments at  
2 site at HCFA. And I'll ask you some questions  
3 about this later. But in later footnote 1 on the  
4 fourth page of the document --

5 A. Yes.

6 Q. -- if you would read that. Or I'll  
7 read it into the record and you can follow along.

8 A. Is this --

9 Q. This is ASCO's comment to the proposed  
10 rule. ASCO wrote "We note an apparent  
11 discrepancy between the proposal as discussed in  
12 the preamble and the text of the proposed  
13 regulation. The preamble refers to the" --  
14 underlined -- "published average wholesale price  
15 whereas the proposed regulation (section 415.34)  
16 refers to the 'national average wholesale price  
17 of the drug as determined by HCFA.'

18 "Since the underlying rationale of the  
19 proposal is that AWP as published in sources such  
20 as the" -- underlined -- "Red Book" -- end  
21 underline -- does not reflect the true price, any  
22 reference in the regulation must be to" --

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1 underlined -- "published AWP. Insofar as the  
2 regulation suggests that HCFA could determine  
3 true average wholesale price and then pay only 85  
4 percent of that, it is plainly inconsistent with  
5 the rationale of the rule."

6 A. Sure sounds like NMC and ASCO were  
7 talking with each other.

8 Q. But they had the same criticism,  
9 correct?

10 A. Yes.

11 Q. Do you recall discussing that with  
12 anyone?

13 A. No. But I agree with them in the  
14 interpretation, their interpretation of the  
15 inconsistency.

16 (Exhibit Abbott 301 was marked for  
17 identification.)

18 BY MR. TORBORG:

19 Q. Ms. Buto, this is a copy of the final  
20 rule, excerpts of it that I've printed off  
21 Westlaw.

22 A. Mm-hmm.

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1 Q. I've printed off the sections that  
2 seemed relevant to reimbursement of drugs because  
3 otherwise I would probably kill a number of  
4 trees.

5 A. Right.

6 Q. Does this appear to you to be a copy of  
7 some of the final rule?

8 A. You know, it's been a long time but I'm  
9 going to say it looks familiar.

10 Q. And in the final rule -- if I could ask  
11 you to turn to page 56 first under the section  
12 payment for drugs --

13 A. Mm-hmm.

14 Q. -- there's a comment that states "We  
15 received a great many comments on this issue  
16 primarily from oncologists indicating that our 85  
17 percent standard was inappropriate. The thrust  
18 of most of the comments was that many drugs could  
19 be purchased for considerably less than 85  
20 percent of AWP, particularly multisource drugs,  
21 while others were not discounted.

22 "Other commenters suggested that while

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1 pharmacies and perhaps large practices could  
2 receive substantial discounts on their drug  
3 purchases, individual physicians could not. The  
4 bulk of the comments suggesting alternatives to  
5 our proposal indicated that the amounts paid  
6 should be based on actual or estimated  
7 acquisition costs."

8 And then if we could skip a paragraph  
9 and go to the response, the rule states "After  
10 considering all the comments on this issue we  
11 have decided to modify the proposed policy.  
12 Payment for drugs would be based on the lower of  
13 the national AWP or the Medicare carrier's  
14 estimate of actual acquisition costs.

15 "Since there can be many wholesale  
16 prices listed for each drug because of multiple  
17 sources for the drug, we are defining the  
18 national AWP as the median price for all sources  
19 of the generic form of the drug. Estimated  
20 acquisition costs would be based on individual  
21 carrier estimates of the costs that physicians,  
22 or other providers as appropriate, actually pay

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1 for drugs."

2 And in that sentence in your final rule  
3 the reference to national AWP was to what?

4 A. Say that again.

5 Q. The reference to the term AWP in this  
6 regulation was referring to what?

7 A. Well, it sounds like they're -- I guess  
8 the thing that I'm stuck on is that it's defined  
9 as a median price for all sources of the generic  
10 form of the drug. It doesn't seem to address the  
11 brand where there is no generic substitution.  
12 The national AWP is a median price for all  
13 sources of the generic form of the drug.

14 Q. My question I think was a little  
15 simpler one than than.

16 A. Okay. Sorry.

17 Q. What does AWP mean in that language?

18 A. Average wholesale price? Is that what  
19 you mean?

20 Q. Yes. Does it refer to the prices in  
21 Red Book and other compendia?

22 A. It doesn't seem to.

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1 Q. It does not explicitly there, correct?

2 A. It's not explicitly here.

3 Q. Let's go, if we could to section --

4 page 265 at the end of the document. And if you  
5 would also have side by side the proposed rule  
6 that we looked at previously --

7 A. Right.

8 Q. Do you have that in front of you?

9 A. Mm-hmm.

10 Q. Under the final rule the methodology  
11 section B states "Payment for a drug described in  
12 paragraph A of this section is based on the lower  
13 of the estimated acquisition cost or the national  
14 average wholesale price of the drug," correct?

15 A. Yes.

16 Q. The proposed rule had stated under B,  
17 payment rule, "Except as specified in paragraph D  
18 of this section, payment for drugs furnished  
19 incident to a physician's service is limited to  
20 85 percent of the national average wholesale  
21 price as determined by HCFA." And it's that "as  
22 determined by HCFA" language that NMC and ASCO

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1 had raised an issue with, correct?

2 A. Mm-hmm.

3 Q. And in the final rule you deleted that  
4 reference to "as determined by HCFA," correct?

5 A. Correct.

6 Q. And do you know the purpose of that  
7 deletion?

8 A. I think we must have -- although I  
9 don't really remember this -- agreed with their  
10 characterization if the national average  
11 wholesale price was our way of computing a more  
12 accurate cost then saying that we wanted to pay  
13 85 percent of that would be unreasonable.

14 So it seemed to be confusing to match a  
15 national average wholesale price that was based  
16 on some degree of rigor in developing what the  
17 actual cost was and taking only 85 percent of  
18 that and reimbursing at that level. So I think  
19 that's what we were responding to there in  
20 dropping the reference to "as determined by  
21 HCFA."

22 Q. If I could ask you to go to page 24 of

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1 the final rule. And I'm referring to the page  
2 numbers on my printout, not any particular number  
3 in the Federal Register. There's a section that  
4 talks and it's subsection F. Do you see that?  
5 "Low contrast media (LOCM)"?

6 A. Yes.

7 Q. What is low osmolar contrast media?

8 A. It's -- contrast material is used to do  
9 sort of imaging studies. And low osmolar  
10 contrast media were developed because some people  
11 have a very bad allergic reaction to the more  
12 traditional contrast media. So -- and these are  
13 called non-ionic contrast media.

14 The issue was -- and I'm just trying to  
15 see if this is reflected here. The issue was  
16 every patient doesn't need this. It's a lot more  
17 expensive. But it's essential for somebody who's  
18 allergic to the traditional media. So I'm  
19 looking at this to see if this was addressing  
20 that issue.

21 (Reading) Okay. This deals with  
22 a different issue then. This is really about --

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1 sorry. The situation I was talking about, which  
2 is a difference in coverage, if you will, existed  
3 more in a hospital setting. This one is trying  
4 to establish how you pay for these.

5 Q. And it says "We will pay separately for  
6 LOCM if it is used for patients with specified  
7 characteristics under the standard methodology  
8 for the payment of drugs generally," correct?  
9 And those are the provisions we just looked at,  
10 correct?

11 A. Right. And the phrase "patients with  
12 specified characteristics" -- the meaning of that  
13 is we are not paying for it for everybody but  
14 we're going to use the standard methodology.

15 Q. And when you -- in the next sentence it  
16 appears you summarize the standard methodology  
17 for the payment of drugs generally; is that  
18 right?

19 A. Yes.

20 Q. And you state "That is, we will base  
21 payment on the lower of the estimated actual cost  
22 or the published wholesale price of the drug"; is

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1 that right?

2 A. (Nods head).

3 Q. And the word "published" refers to --

4 A. It seems to be a change from the  
5 language elsewhere in the final rule where we  
6 used the national average wholesale price instead  
7 of -- here we're using the published wholesale  
8 price.

9 Q. If you go to the second to the last  
10 page, page 247 of the document, under section E,  
11 you understand that in drafting these regulations  
12 typically you perform an impact assessment,  
13 correct?

14 A. Yes.

15 Q. This section E discusses effects of  
16 separate payment for drugs and states -- I'll  
17 skip the first couple sentences and read the  
18 sentence that starts with "Under our final  
19 policy." It states "Under our final policy  
20 carriers will be instructed to base payment for  
21 drugs on the lower of the estimated acquisition  
22 cost or the national average wholesale price of

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1 the drug as published in the Red Book and similar  
2 price listings."

3 Is it fair to say, Ms. Buto, that the  
4 intent of CMS in drafting this provision with  
5 respect to average wholesale price was to refer  
6 to the prices that are found in Red Book and  
7 similar price listings?

8 A. Yeah. The intent, though,  
9 unfortunately, which was never really achieved,  
10 was that was the fallback if the agency couldn't  
11 come up with estimated acquisition cost. The  
12 agency never really came up with estimated  
13 acquisition cost.

14 Q. There were two possibilities for  
15 determining the payment amount, one was estimated  
16 acquisition cost. If you were not able to find  
17 that for a particular drug then it would be  
18 reimbursed under the intent of your regulations  
19 by virtue of the average wholesale price as  
20 published in Red Book and similar price listings,  
21 correct?

22 A. Yes. That's certainly the result. The

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1 -- I can't even remember the deliberations and I  
2 wouldn't speak of them anyway, as you know. But  
3 I do know that our expectation would be that we  
4 would be able to do estimated acquisition cost  
5 surveys. Unfortunately it didn't work out that  
6 way.

7 MR. TORBORG: We're at 5:00. We've  
8 probably got to stop for the day.

<sup>9</sup> THE WITNESS: Okay. Thank you.

10 THE VIDEOGRAPHER: This concludes tape  
11 5 in the deposition of Kathleen Buto. We adjourn  
12 for the day at 5:06.

13 (Whereupon, at 5:06 p.m. the  
14 deposition was adjourned.)

17 KATHLEEN BUTO  
18 Subscribed and sworn to and before me  
19 this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_\_.  
20

<sup>22</sup> Notary Public

## Notary Public

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